

AMENDMENTS TO THE DRAWINGS

Please amend Fig. 6 as shown in redline in the Marked-Up Version attached.
A clean copy of the Replacement Drawing is also enclosed.

REMARKS

Claims 1-4, 6-14, 16-24, 26-27, 30-41, and 44-48 are pending for the Examiner's review and consideration, of which claims 5, 15, 25, and 37-43 were presently withdrawn from consideration. Claims 1, 10, 16, 18-19, 30, and 37 are presently amended. Claims 28, 29, 42, and 43 have been cancelled without prejudice, and the recitations of claim 28 have been added to claim 30. Claim 37 has been amended to depend from claim 7. New claims 44-48 have been added and are fully supported by the originally filed specification, claims, and drawings. No new matter has been entered by these amendments, and the right is reserved to prosecute any cancelled subject matter in continuing or divisional applications.

The specification and drawings are presently amended since it was noted that the numeral 50 was unintentionally used to designate two different elements, and that the lateral sides of the vertebra had inadvertently not been numbered in Fig. 6. The amendment renumbers the lateral sides of the vertebra with numeral 51, and these numerals have been appropriately added to Fig. 6. These amendments are fully supported, for example in the amended paragraphs themselves, on pages 9 and 13.

Claims 1-4, 6-14, and 26-36 were rejected under 35 U.S.C. § 112, second paragraph, with the indication that claim 1 lacked antecedent basis for the term "the contacting member." As amended, this claim now provides such antecedent basis. Claim 34 has been similarly amended to provide antecedent basis for the same term. With respect to the definition of facing axially or axial and lateral directions, these terms are definite to those of ordinary skill in the art, because the implant is for vertebra, which naturally have axial and lateral axes. Several claims have been modified to further clarify this, by reciting these as vertebral directions or axes, such as claims 10 and 19, and new claims 45, 46, and 48. Claim 18 has been amended to define that the central portions are pivotally connected to each other.

Claim 19 was also rejected under § 112, second paragraph, with the indication that the Examiner did not understand what is meant by the recitations of this claim. Specifically, claim 19 defines at least one protrusion that is associated with the top or the bottom endplate. This protrusion is received in an opening in the other of the endplates. The opening is larger than the protrusion in the direction of rotation of the endplates, which is defined as being a rotational direction about the pivot. This difference in size permits a limited axial rotation. An example of this is provided in the description of the preferred

embodiment, such as in the second full paragraph on page 12 of the application, in which openings 80 are sufficiently larger than lugs 77 to allow but limit the axial rotation. No amendment is believed to be necessary to these terms in claim 19, since one of ordinary skill in the art would find these recitations to be definite.

Claims 1, 6, and 13 were rejected under 35 U.S.C. § 102(b) as anticipated over Chauvin '763.

Claim 1 is directed to a vertebral disk prosthesis that is structured to be disposed adjacent to at least one vertebral body. The prosthesis has at least one contacting member that has at least two movable lateral portions. The lateral portions are movable between a contracted position, in which the member has a first width smaller than the width of the vertebral body, and expanded position in which the contacting member has a larger width. This expanded width is sufficient so that the member can abut the periphery of the vertebral body, including at the opposite sides of the vertebral body. As explained on page 13 of the application, extending all the way to the lateral sides and at the periphery of the body allows the prosthesis to support and contact the bone where the bone is stiffer. This improves the longevity of the implantation since the bone is better able to support weight along its outer edges. Having a prosthesis that can be expanded to extend to the opposite lateral sides of the vertebra provides the benefit that a much more solid support of the adjacent vertebra can be obtained, especially to withstand lateral bending of the spine, which was typically not obtainable in traditional prostheses. In addition, it is surprising over the prior art that a prosthesis can have a narrower lateral implantation-configuration where it can be easily implanted from the front of the spine, bypassing large blood vessels and muscles that are present in the front of the spine, but which can then be expanded to support the harder bone on the lateral sides of the periphery of the vertebral body, instead of being laterally limited to supporting softer bone on the face of the vertebral body, or not reaching the lateral sides thereof.

On the other hand, Chauvin teaches an expandable cage that is meant for implantation from the back of the spine, and has branches 5 that are expanded in two different directions by spacer 2. The Chauvin cage is incapable of expanding sufficiently to reach the lateral sides of the periphery of the vertebral body, and is incapable of providing the surprising benefits from the claimed invention. Consequently, claim 1 is patentably distinct over Chauvin.

Claims 1-4, 6-12, 14, 16-20, 22-24, and 26-33 were rejected under 35 U.S.C. § 102(e) as being anticipated by Jackson '206. Additionally, claims 21 and 34-36 were rejected under 35 U.S.C. § 103 as being obvious over Jackson. Jackson is related to a spinal fusion cage that is incapable of expanding in a lateral direction. While claim 1 defines that the lateral portions of the recited prosthesis contract and expand to provide a lateral width, which is compared with the lateral width of the vertebral body (the lateral width of a vertebral body is well understood by persons having ordinary skill in the art as being along a lateral spinal direction), the only movement that the Jackson cage is capable of is in an axial direction, and this is before the implantation is complete with the cage engaging the vertebrae.

Consequently, the surprising benefits of the claimed invention are neither possible in Jackson nor are they suggested as being possible.

Claim 2 further defines that the shape of the member in the expanded position generally corresponds to the periphery of the vertebral body. This is apparent in the preferred embodiments of the application and the descriptions of the drawings, which allow the shape of the members to be readily compared to the shape of the vertebral body face for the purposes of illustration. There is no suggestion or motivation to modify the Jackson cage to provide this shape, nor would this be readily doable since it is not even clear how such a shape could be achieved while maintaining the general configurations theretaught in the references.

Claim 10 defines a gripping portion that faces generally in a vertebral axial direction, which is moved axially by a wedge. As noted above, Jackson does not disclose or suggest any movable portions that can be moved in two different directions, such as laterally and axially.

With respect to claim 12, which the Examiner rejected over Jackson, alleging that Jackson teaches a ratchet, shown as members 433 and 351, Applicant notes that a ratchet is a well-known mechanical construction which is very different from the flange 451 and groove 433 of Jackson. A ratchet is well known to be a mechanism that permits motion in a single direction, but not in the opposite direction, and typically includes teeth or a pawl that slides over other teeth to allow this. The groove and flange 451 are totally incapable of performing as a ratchet and certainly do not qualify as a ratchet themselves. There is no teaching or suggestion of claim 12 in Jackson.

Claim 14 and new claim 44 define percentages of the periphery of the vertebral body that the prosthesis abuts and supports in the expanded position. These

percentages, respectively, are 50% and 75% of the periphery. It is doubtful that the Jackson cage could support any part of the periphery of the vertebral body, and even if it were long enough to contact one or both of the longitudinal ends of the vertebral body, this percentage would be tiny compared to the claimed percentages. Consequently, claims 14 and 44 are patentably distinct from the references on their own merits.

Claim 16 defines that the prosthesis has top and bottom endplates, which engage two different vertebral bodies. These two endplates are pivotably connected to allow the vertebral bodies to pivot with respect to each other when the endplates are engaged with the vertebral bodies. On the other hand, the Jackson implant is a cage, which by definition and description locks the two vertebral bodies in a fixed position, but does not allow any articulation thereof. It is clear that when the Jackson cage is fully implanted, there is absolutely no motion permitted between the surfaces that touch the vertebral bodies. There is thus no teaching or suggestion of claim 16 in any of the references.

Additionally, the claims that are dependent on claim 16 further define preferred features that allow the articulation of the two vertical bodies, which is impossible when using the Jackson cage. Claim 17, for example, defines a sloped surface facing one of the endplates to permit but limit pivoting between the endplates. Claim 18 defines the central portions of the endplates that are pivoted with respect to each other, and Jackson does not have any two central portions that can be pivoted with respect to each other and which are between any kind of pivoting lateral portions. Claim 19 defines protrusions received in openings that are larger than the protrusions to allow and limit rotational pivoting. Claim 20 specifies that the pivot is a universal pivot. With respect the universal pivot, it is noted that the office action generally states that Jackson has a universal pivot. As with the definition of a ratchet explained above, a universal pivot is a well known structure in the mechanical arts which allows pivoting in more than one axis at the same time; there is no such structure in Jackson. None of the recited structures in these claims would have a place in the cage of Jackson, which intentionally does not allow for any pivoting between adjacent vertebrae or any type of endplates once the implant is engaged with the vertebrae. Claim 38 defines a prosthesis that can be expanded in vertebral lateral and axial directions. Lateral portions are provided to expand in the lateral direction, and an axial portion is provided to expand in the axial direction. As indicated above, legs of the Jackson cage all expand along a single axial vertebral direction, but there are no members that can expand in lateral vertebral directions. Thus, this claim is also patentably distinct from the references of record.

With respect to the obviousness rejections, claim 34 defines first and second contacting members that abut adjacent vertebral bodies and that there is a bushing that is disposed between and in supporting association with the contacting members when the prosthesis is implanted between the vertebral bodies. The bushing is defined as comprising a gel, and is configured for absorbing shock between the vertebral bodies. The office action alleges that it would be obvious to place a gel bushing between the threads 64 and threaded portion 33 of number 10 in Jackson, and that this is because gel bushings between the threads of a screw and a threaded member for the purpose of reducing friction and forming a solid connection is well known. The Examiner is hereby respectfully requested to provide evidence that this is well known, since this is not found in any of the references of record. It is believed that the Examiner is thinking of plastic fittings, such as those found in locknuts, but these are not typically made of a gel. Additionally, even if a gel bushing were to be placed about the threads 64 of Jackson, this still would not result in a bushing in supportive association between two different contacting members, since the threaded portion 64 is surrounded entirely by the female threaded portion. Additionally, since the cited portion is merely received in a screw hole, there would be no reason to add any kind of bushing for shock absorption or support therein, since the stresses between one vertebra and the next are carried around the outside of the hole, and a bushing in the hole would not provide any shock absorption in the Jackson cage between vertebrae. Consequently, there is no suggestion or motivation to modify Jackson as proposed in the office action, and the invention of claim 34 is novel thereover.

Claim 35 defines that the bushing is slidable with respect to the first member to reduce shearing within the bushing during relative motion between the first and second members. It would be completely unclear how this could possibly be applied to the threaded portion 64 of Jackson, since this would not be between the moving parts in an area of relative movement. There is, in fact, no teaching or suggestion of the invention of claim 35 in the references of record.

Claim 36 further defines that the lateral portions are movable to change the lateral width of the prosthesis, which as explained above, is not possible in any portion of the Jackson cage. Consequently, claim 36 is also patentable on its own merits.

New claims 45-48 are directed to the elected group and species. Claim 45 defines top and bottom endplates, which respectively supportably engage first and second vertebral bodies, allowing pivoting between the bodies when the implants are engaged

therewith. As described above, no pivoting is possible once the Jackson cage is implanted. Claim 46 further defines a structure to support the wedges, which is not taught or suggested in Jackson or Chauvin; claim 47 defines that the axial portion of each of the top and bottom endplates is a single axial portion (for example, as shown in Fig. 2); and claim 47 defines the preferred embodiment of the pivoting that is allowed by the claimed structure between the adjacent vertebral bodies when the prosthesis is implanted. None of these features are taught or suggested in the references of record.

It is believed that the entire application is presently in condition for allowance. Should any issues remain, a personal or telephonic interview is respectfully requested to discuss the same in order to expedite the allowance of the application.

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Date

Respectfully submitted,



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Marked-up Version

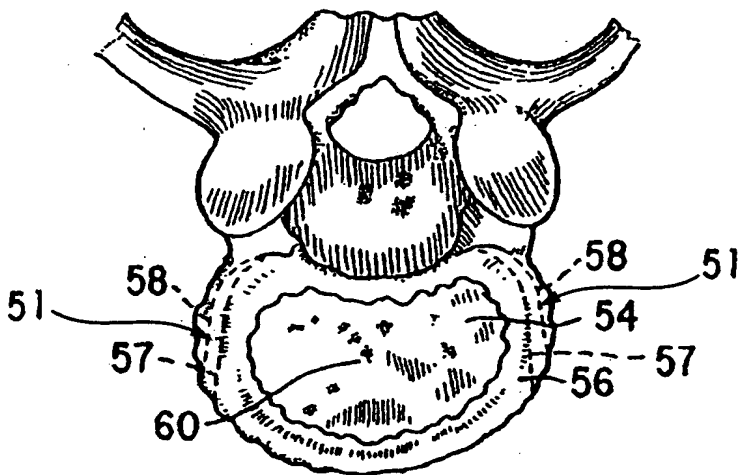


FIG. 6

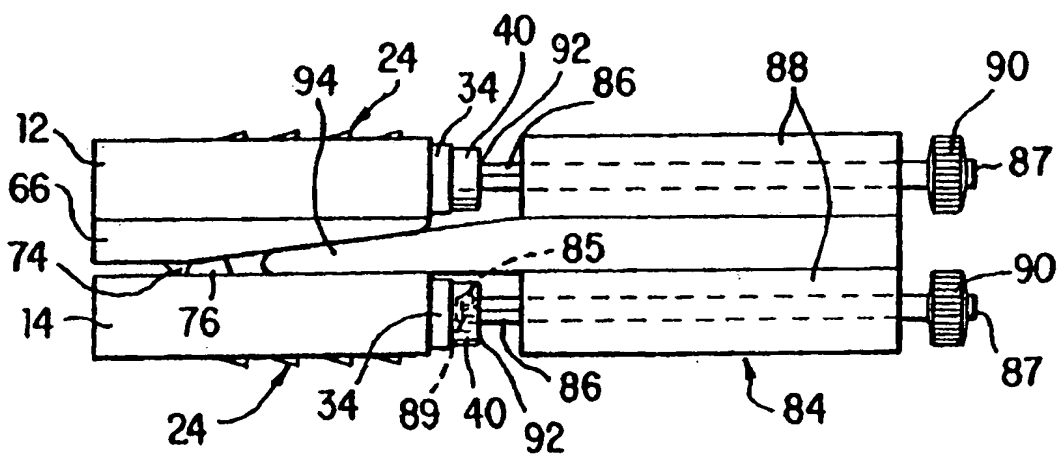


FIG. 7